Remarks

The above Amendments and these Remarks are in reply to the Office Action mailed August 18, 2004. No fee is due for the addition of any new claims. A Petition for Extension of Time to Respond is submitted herewith, together with the appropriate fee.

Claims 1-23 and 26-36 were pending in the Application prior to the outstanding Office Action. In the Office Action, claims 1-23 and 26-36 were rejected. The Applicant cancels claims 7 and 8, amends claims 1, 3, 18, 21-23, 29 and 33-34, and adds new claims 37-40. Accordingly, Claims 1-6, 9-23, and 26-40 are currently pending. Reconsideration of the claims is respectfully requested.

Claim Rejections under 35 U.S.C. 112

Within the Office Action, claims 16-20 as well as claims 22 and 23 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, it is stated within the Office Action that the configurations in Claims 16-20 and 22-23 appear to conflict one another. The Applicant respectfully disagrees.

Within the present specification, Figure 1E illustrates a perspective view of an end plate 110 of the implant 100. As shown in Figures 1A and 1E, the end plate 110 has a first surface 112 and a second surface 116. The second surface 116 of the end plate 110 preferably has a socket 150 therein. The keel 114 is shown in Figures 1A and 1E disposed on the first surface 112 and extending between the anterior and posterior sides of the end plate 110. The socket 150 is disposed on the second surface 116 and extends between the right lateral and left lateral sides of the end plate 110. Thus, the socket 150 is oriented along a plane which is perpendicular to the plane along which the keel 114 is oriented. For at least these reasons, dependent Claim 16 is fully supported by the specification and the figures in the present application.

The socket 150 can alternatively be disposed along the second surface 116 to extend between the anterior and posterior sides of the end plate 110. As stated above, the keel 114 is shown in Figures 1A and 1E disposed on the first surface 112 and extending between the anterior and posterior sides of the first end plate 110. Thus, the socket 150 can be oriented along a plane which is parallel with the plane along

which the keel 114 is oriented. For at least these reasons, dependent Claim 17 is fully supported by the specification and the figures in the present application.

For the reasons stated above, the socket of the second piece can be oriented parallel or perpendicular to the orientation of the keel extending from the second surface. For at least these reasons, dependent Claims 19 and 20 are fully supported by the specification and the figures in the present application. Dependent Claim 18 has been amended to be dependent on Independent Claim 1. Accordingly, Claims 16-20 are allowable.

Regarding Claims 22 and 23, the sagittal plane is known in the art as the plane which extends through the spine from the front to the back or vice versa. As stated above, the keel of the implant 100 extends between the anterior and posterior sides of the implant 100. Additionally, the socket in the upper implant 110 extends perpendicular to the sagittal plane between the right lateral and left lateral sides of the implant 110, as shown in Figure 1E. Thus, Claim 22 is sufficiently supported in one embodiment, as shown in Figure 1E. In addition, the socket in the lower implant 120 extends between the anterior and posterior sides of the implant 120, parallel to the sagittal plane, as shown in Figure 1G. Claim 23 has been amended to recite that the concave socket is in the lower implant. Accordingly, Claim 23 is fully supported by the specification. For at least these reasons, Claims 22 and 23 overcome the rejections and are in a condition for allowance.

Rejections Under 35 U.S.C. 102

Within the Office Action, claims 1, 4-12, 14, 21-23 and 35-36 have been rejected under 35 U.S.C. 102 as being anticipated by U.S. Patent Publication 2004/0106998 to Ferree (hereinafter "Ferree"). In addition, claims 1-23 and 26-36 have been rejected under 35 U.S.C. 102 as being anticipated by U.S. Patent 6,706,070 to Wagner et al (hereinafter "Wagner"). The Applicant respectfully disagrees.

The present invention is directed to an implant which has a first end plate and a second end plate, whereby the first end plate attaches to a first vertebral body and the second end plate attached to an opposed second vertebral body. The first end plate and the second end plate both have an inner surfaces which face one another. Preferably along the inner surface of the first end plate is a first socket and along

the inner surface of the second end plate is a second socket. A spacer having a first bar and a second bar which are preferably perpendicular to one another is configured to be positioned between the inner surfaces of the first and second end plates. The bars of the present spacer preferably sit in the respective first and second sockets such that the first end plate and the second end plate are able to move with respect to one another to accommodate flexion, extension and lateral bending of the vertebral bodies.

Ferree

Ferree teaches a multi-axial artificial disk replacement having a cruciate-shaped axle 102 positioned therein. The axle 102 is positioned between a top component 104 and a bottom component 104'. The top component 104 has apertures on the sides of the inner surface of the top component 104, whereby the apertures engage the ends of the axle 102. The bottom component 104' also has two apertures on the sides of the inner surface of the bottom component 104 and are perpendicular to the apertures of the top component 104. The apertures of the bottom component 104 receive the other ends of the axle 102.

In contrast to independent Claims 1, 35 and 36 of the present invention, Ferree does not teach first and second sockets, whereby the crossbar member is at least partially received within the first and second sockets. As stated in the present application, it is preferred that the first and second end plates of the present device have perpendicularly oriented sockets in their inner surfaces, whereby the crossbar spacer is received in the sockets. Accordingly, Ferree is distinguishable from the present invention. For at least these reasons, Claims 1, 35-36 are allowable over Ferree.

Claims 4-12, and 14 were also rejected under 35 U.S.C. 102(e) as being anticipated by Ferree. Claims 4-12 and 14 are dependent on independent Claim 1. As stated above, Claim 1 is allowable over Ferree. Accordingly, Claims 4-12 and 14 are allowable for being dependent on an allowable base claim.

In contrast to independent Claim 21, the Ferree implant does not teach a first concave socket in the second surface of the upper implant. Additionally, the Ferree implant does not teach a second concave socket in the second surface of the lower implant. Further, Ferree does not teach a crossbar spacer received in the first and second concave sockets, as recited in Claim 21. Instead, Ferree discloses adjacent to the inner surfaces of the top and bottom components through which the cruciate axle 102 extend.

Accordingly, Ferree is distinguishable from the present invention. For at least these reasons, Claim 21 is allowable over Ferree.

Claims 22 and 23 were also rejected as being anticipated by Ferree. Claims 22 and 23 are dependent on independent Claim 21. As stated above, Claim 21 is allowable over Ferree. Accordingly, Claims 22 and 23 are allowable for being dependent on an allowable base claim.

Wagner

Wagner teaches an alignment device that fuses adjacent vertebrae together. In particular, the Wagner device has a height adjustment feature which alters the vertical height between the engaging plates to achieve the natural shape of the spine when the vertebrae are fused. Figure 9 in Wagner illustrates one embodiment of the device, wherein the device includes two "I" struts which engage slots in the inner surfaces of the engaging plates. The struts do not allow the upper or lower engaging plates to pivot about the struts, but instead merely alter the height between the upper and lower engaging plates. It is stated in Wagner that each of the struts contain a hinge pin 70 to allow an upper member 72 of the strut to pivot with respect to a lower member 74 of the strut. However, this is to allow the ends of the struts to be properly aligned with the slots of the engaging plates when a height difference exists between the first and second struts.

In contrast to the present invention, the struts 30 shown in Figure 9 are not similar to the crossbar spacer of the present invention. As expressly disclosed in the figures (Figures 2A-2D) and the description of the present specification, the crossbar spacer 130 preferably has a first beam and a second beam which are perpendicular to one another. The configuration of the crossbar spacer 130 allows the first end plate 110 and/or the second end plate 120 to pivot about the crossbar spacer 130 to accommodate flexion, extension and lateral bending of the vertebral bodies. The "I" strut 30 in Wagner is not designed nor configured to allow the upper and lower engaging plates to move like such. Therefore, one skilled in the art would not view the strut 30 in Wagner as reading on the crossbar spacer in the claims of the present invention.

Regarding the embodiments shown in Figures 38 and 42-49 in Wagner, none of the devices shown read upon independent Claims 1, 21, 26, 35 and 36 of the present application. Each of the embodiments

in Figures 38 and 42-49 include 2 or more screws positioned between the upper and lower engaging plates. The screws are each attached to a non-moveable cam block in the center, whereby each screw includes a movable cam block thereon. The screws, when turned, cause the cam block to move towards the outer edges of the upper and lower engaging plates, thereby forcing the upper and lower engaging plates away from each other. Thus, the screws and cam blocks of the Wagner device only serve to adjust the height between the upper and lower engaging plates. The upper and lower engaging plates in the Wagner device, however, do not pivot or even slightly move. In fact, the upper and lower engaging plates are not supposed to move, because the Wagner device is a vertebrae fusing device.Independent Claims 1, 21, 35 and 36 each recite that at least one of the upper and lower end plates are able to move about the spacer, which is not taught in Wagner. Accordingly, Claims 1, 21, 35 and 36 are distinguishable over Wagner and are thus in a condition for allowance.

Claims 2-20, 22, and 23 were also rejected under 35 U.S.C. 102(e) as being anticipated by Wagner. Claims 2-20 are dependent on independent Claim 1. As stated above, Claim 1 is allowable over Wagner. Accordingly, Claims 2-20 are allowable for being dependent on an allowable base claim. Claims 22 and 23 are dependent on independent Claim 21. As stated above, Claim 21 is allowable over Wagner. Accordingly, Claims 22 and 23 are allowable for being dependent on an allowable base claim.

Regarding Independent Claim 26, there is no hint, teaching or suggestion in Wagner that the screws or "I" struts have a first beam mounted at least partially above and across a second beam, as recited in Claim 26. For at least these reasons, independent Claim 26 is distinguishable over Wagner. Accordingly, Claim 26 is allowable over Wagner.

Claims 27-34 were rejected in the office action as being anticipated by Wagner. However, Claims 27-34 are dependent on independent Claim 26. As stated above, Claim 26 is allowable over Wagner. Accordingly, Claims 27-34 are allowable for being dependent on an allowable base claim.

Rejections under 35 U.S.C. 103

Within the Office Action, claims 15-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree in light of PCT Patent Application WO 01/01893 to Marnay. For the reasons stated above, Ferree is not considered prior art in relation to the present application. Accordingly, Claim

1 is not anticipated by Ferree, and one skilled in the art would, therefore, have no motivation to utilize Ferree with Marnay to reach the invention claimed in Claims 15-20. Therefore, Claims 15-20 are patentable and thus allowable over Ferree and Marnay, individually or in combination.

New Claims

The Applicant has added new claims 37-40. The Applicant submits that the new claims are allowable over the prior art, are fully supported by the specification and do not contain new matter. The Applicant respectfully requests considerations of new Claims 37-40.

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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